Section 5 – 510(k) Summary

K110867

JUL 20 2011

Device Owner and Manufacturer

CPAC, Inc

2364 Leicester Rd

Leicester, NY 14481

Contact person

Jeffrey Crane

2364 Leicester Rd

Leicester, NY 14481

Phone: 585-382-3223

Fax: 585-382-3736

Summary prepared on June 3, 2011

Device

Trade name: Steri-Dent Self-Seal Nylon Pouch

Common name: Sterilization Wrap

Classification name: Wrap, Sterilization (21 CFR 880.6850, Product Code FRG)

Predicate Device

The Steri-Dent Self-Seal Nylon Pouches are substantially equivalent to the Winner Self Seal Sterilization Pouch both of which are single use sterilization wraps. The predicate device is legally marketed under 510(k) K051242.

Device Description

The Steri-Dent Self–Seal Nylon Pouches are single use sterilization wraps that provide a means for health care providers to enclose metal instruments, which are sterilized in a dry heat sterilizer, and to maintain sterility of the instruments until they are used. The pouches can be used in dry heat sterilizers with a sterilization cycle of 1 hour (60 minutes) operating at 160°C (320°F) such as the Steri-Dent Model 2100 and 3100. The nylon pouches will maintain the sterility of the instruments for a maximum of 30 days. If the instruments inside the pouch are not used within 30 days after being sterilized, they should be removed, placed in a new bag and re-sterilized.

Indications for Use

The Steri-Dent Self-Seal Nylon Pouch is intended to be used to allow sterilization of enclosed medical instruments by a dry heat sterilizer operating at 160°C (320°F) for 1 hour (60 minutes) and also to maintain the sterility of the enclosed instruments for 30 days after sterilization.

Technological Characteristics Comparison

Below is a comparison of the technological characteristics of the Winner Self Seal Sterilization Pouch and the Steri-Dent Self-Seal Nylon Pouch

Characteristic	Predicate Device – Winner®	Device – Steri-Dent
Single Use or Reuse	Single Use	Single Use
Pouch Material	Medical Grade Paper and plastic film	Nylon
Seal Method	Self Seal adhesive strip	Self Seal adhesive strip
Sterilization Method	Steam or ethylene oxide (EtO)	Dry Heat
Sterilization Temperature	Steam - 121°C (250°F) EtO – no recommendation	160°C (320°F)
Sterilization Time	Steam – 15 minutes EtO – no recommendation	1 hr (60 minutes)
Smallest pouch size	3" x 8"	2" x 10"
Largest pouch size	18" x 22"	9.5" x 13"

The technological difference between the Steri-Dent device and the predicate device is material differences due to the type of sterilization method used. The predicate device is designed to be used for steam or gas (EtO) sterilization and so must provide a means for the steam and gas to penetrate in and out of the pouch. This is accomplished by using a medical grade paper on one side of the pouch to allow this transfer of air. The Steri-Dent nylon pouch is designed to be used for dry heat sterilization and so does not require air to penetrate the pouch, only thermal energy. This technological difference allows the new device to be made of entirely of nylon which allows for the transfer of heat in and out of the pouch while providing an excellent microbial barrier.

Non-Clinical Performance Data

Safety

The biocompatibility tests demonstrated that the pouch materials are not toxic to the health care provider or the patient.

Effectiveness of Sterilization of Enclosed Instruments

Half cycle efficacy studies performed on both the model 2100 and 3100 dry heat sterilizers using the nylon pouches demonstrated that the heat penetrated through the pouch and sterilized the instruments inside.

Effectiveness of Maintaining Sterility of Enclosed Instruments

The aerosol challenge test, 30 day shelf life test and material compatibility tests demonstrated that the pouches maintained the sterility of the enclosed instruments.

Conclusion

The non-clinical tests demonstrate that the nylon pouch is as safe and effective as the predicate device in providing health care providers a single use pouch to keep sterilized medical instruments sterile until their use. The pouch is made entirely of nylon with an adhesive seal tape which the biocompatibility tests prove to be safe for direct patient contact. The half cycle tests performed using a dry heat sterilizer demonstrates that the pouch allows for the transfer of heat to enable sterilization of the enclosed instruments. The ability of the nylon pouch to maintain the sterility of the enclosed instruments after sterilization is proven by a number of tests. The material compatibility shows the high strength and puncture resistance of the nylon material. The 30 day shelf life and aerosol challenge tests show the nylon material and adhesive seal tape provide the microbial barrier required to keep the instruments sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Jeffery S. Crane
Engineering Project Manager
CPAC, Incorporated
2364 Leicester Road
P.O. Box 175
Leicester, New York 14481

JUL 20 2011

Re: K110867
Trade/Device Name: Steri-Dent / Steri-Sure Self Seal Nylon Pouches
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 5, 2011
Received: July 6, 2011

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutF DA/CentersOffices/CDR H/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use Statement

501(k) Number: K110867

Device Names: Steri-Dent / Steri-Sure Self-Seal Nylon Pouches

Indications for Use

The Steri-Dent / Steri-Sure Self-Seal Nylon Pouch is intended to be used to allow sterilization of enclosed medical instruments by a dry heat sterilizer operating at 160°C (320°F) for 1 hour (60 minutes) and also to maintain the sterility of the enclosed instruments for 30 days after sterilization.

Prescription Use_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___XX___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY),

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110867